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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,239	12/21/2001	Michael Weickert	0067.00	6675

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NEKTAR THERAPEUTICS
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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,239	WEICKERT ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted April 16, 2004 is acknowledged.

Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 40, and 42-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al. (US 5,965,156), in view of Staniforth et al. (WO 97/03649, IDS) and Gorden et al. (US 6,077543, IDS).

3. Proffitt et al. teaches an amphotericin liposome powder with diameters less than 2 um, which may be obtained through a spray drying of an acidified solution of amphotericin. The powders characterized as stable and less toxic. See, particularly, column 4, line 55 to column 7, line 35, and the claims. Further, it is well known that amphotericin B is useful for treating fungal infections. See, particularly, column 1, lines 30-45.

4. Proffitt et al. does not teach expressly a powder contains more than 30% by weight of amphotericin, which is for inhalation.

5. However, Staniforth et al. teaches that powder composition for inhalation generally comprising high concentration of active ingredient, (e.g., 60% or higher by weight). See, the abstract. The optimal particle size for lung inhalation administration is 0.1 um to 5um and leucin is added as anti-adherent material. See, particularly, the abstract. Gordon et al. teaches that

hydrophobic drugs for lung delivery, such as amphotericin B are known to be made into particles less than 5 um in size. See, particularly, column 1, lines 52-67, column 5, line 20 to column 6, lines 62.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a stable amphotericin powder composition for inhalation administration by drying a acidified solution of amphotericin according to Proffitt's method (without adding the other ingredients required for the liposome composition).

A person of ordinary skill in the art would have been motivated to make a stable amphotericin powder composition for inhalation administration by drying a acidified solution of amphotericin according to Proffitt's method (without adding the other ingredients required for the liposome composition) because Proffitt's method is known to provide stable amphotericin composition. Further, making a powder composition suitable for inhalation (i.e., with certain size of the particle) administration, or controlling degradation of the active ingredient during the process of making, is a matter of optimization of a result effective parameter, which is considered within the skill of the artisan, particularly in view of the fact that method of making such powders is well-known in the art (see Staniforth et al. and Gorden et al). See, In re Boesch and Slaney (CCPA) 204 USPQ 215. Further, it would have been obvious to employ a known antifungal agent for treating fungal infection patient.

6. Claims 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Proffitt et al. (US 5,965,156), in view of Staniforth et al. (WO 97/03649, IDS) and Gorden et al. (US 6,077543, IDS) for reasons set forth above, and in further view of Seager et al.

7. Proffitt et al., Staniforth et al. and Gorden et al. take together do not teach expressly the employment of aqueous suspenssion, wet milling and spray drying to make the powder.

8. However, it would have been obvious to one of ordinary skill in the art, at the time the claimed invention was made to employ wet milling-spray drying technique for making a powder because such technique is well known in the art for making fine particles. See, e.g., column 8, line 66 to column 9, line 10.

Response to the Arguments

Applicants' amendments and remarks submitted April 23, 2004 have been fully considered, but are not persuasive with respect to the rejection set forth above.

9. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). One or ordinary skill in the art, possessing the knowledge disclosed in the cited references, would have seen the claimed invention obvious. Particularly, knowing the technique of making a stable polyene particles as disclosed by Proffit, one of ordinary skill in the art would have combine the known knowledge of making polyene aerosol to arrive the claimed invention.

10. Further, it is noted that Proffit teaches dried nonhydrated stable powders. See, particularly, column 5, lines 26-43, and examples 1 in column 8. Therefore, Proffit's method is suitable for make aerosol dried powder.

As to claims 40 and 41, it is further noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see also MPEM 2113).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang

July 9, 2004